No. 06-179

In the Supreme Court of the United States

DONNA S. RIEGEL, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF CHARLES R. RIEGEL,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

INTEREST OF THE *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry, and from every region of the country. An important function of the Chamber is to represent its members' interests in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of vital concern to the Nation's business community.

This is such a case. The Chamber's members include device manufacturers that depend on preemption under the Medical Device Amendments, 21 U.S.C. § 360k(a), as protection against the imposition by state and local governments of burdensome, divergent and even conflicting requirements relating to premarket-approved devices. The Chamber's membership also includes millions of businesses that are subject to the many other statutory schemes and regulations that preempt state and local laws. Accordingly, the Chamber and its members have a substantial interest in ensuring that this Court properly resolves the significant issues raised in this case.

STATEMENT

This case presents important questions about the scope of express preemption under the Medical Device Amendments to

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[1] The parties' letters of consent to the filing of this brief have been filed with the Clerk. Under Rule 37.6 of the Rules of the Court, *amicus curiae* states that no counsel for a party has written this brief in whole or in part and that no person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a). Specifically, the Court is called upon to decide whether, under the framework of analysis set forth in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), Section 360k(a) preempts divergent requirements imposed by state tort law on the design, manufacture, and labeling of a medical device that has "run[] the gauntlet" (518 U.S. at 494) of obtaining premarket approval (PMA) from the Food and Drug Administration (FDA). Like the Second Circuit in this case, the vast "majority of circuits addressing this question" (Pet. App. 2a; *id.* at 23a) have upheld preemption in this setting. So should this Court.

A. The Medical Device Amendments And FDA's Clearance Of New Devices For Marketing

Enacted in 1976, the Medical Device Amendments (MDA) vastly expanded the authority of the FDA to regulate medical devices "to assure the[ir] safety and effectiveness." H.R. Rep. No. 94-853, at 3 (1976). At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." *Id.* at 12; see also *ibid.* (describing MDA as "a balanced regulatory proposal"). Toward the latter end, Congress sought to shield device manufacturers from the "undu[e] burden[]" imposed by differing state laws and regulation by including a preemption provision that contains a "general prohibition on non-Federal regulation." *Id.* at 45.

The MDA classifies medical devices into three categories based on the potential risks of harm. See Pet. App. 7a-9a; *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Devices carrying the highest risks, so-called "Class III" devices, are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or that "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(A)(ii). All post-1976 devices, including the Evergreen Balloon Catheter at issue in this case, initially are automatically considered Class III devices and cannot be

marketed without FDA clearance or approval. *Id.* §§ 360e(a), 360c(f)(1).

Premarket clearance can occur in either of two ways. *First*, FDA evaluates some Class III devices under the PMA process. Characterized by this Court as "exhaustive" (*Buckman*, 531 U.S. at 349) and "running the gauntlet" (*Lohr*, 518 U.S. at 494), the PMA process is the FDA's most stringent form of regulatory review. It "involves a time-consuming inquiry into the risks and efficacy of each device." *Buckman*, 531 U.S. at 348. Only a tiny fraction of new Class III devices go through the PMA process. See Pet. App. 13a (only 32 out of 3180 devices in fiscal year 2005); see also *id.* at 3a (explaining that Second Circuit's decision affects only a "small universe of cases").

The *second* method of obtaining FDA clearance to market new Class III devices is through the so-called "510(k) process." Aimed at fostering competition, the 510(k) process allows a device to bypass the stringent PMA requirements if it is "substantially equivalent" to a "grandfathered" device on the market before passage of the MDA in 1976. See 21 U.S.C. § 360c(l); *Lohr*, 518 U.S. at 494. The 510(k) process "lacks the PMA review's rigor" (*Buckman*, 531 U.S. at 348) and focuses on "*equivalence*, not safety." *Lohr*, 518 U.S. at 493 (internal quotations omitted). "[I]n contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Id.* at 479.

At the conclusion of the PMA process, FDA issues a final order approving the device for marketing if the manufacturer has demonstrated that the device's safety and effectiveness is reasonably assured. 21 U.S.C. § 360e(d)(1)(A). Such an order authorizes marketing the device with the particular labeling (including product warnings) and according to the specific design and manufacturing processes submitted to FDA. The order prohibits changes to the approved labeling, product design, manufacturing process, or construction of the device that would affect its safety or effectiveness without FDA approval. 21 C.F.R. §§ 814.39, 814.80; Pet. App. 9a-10a.

B. The Preemption Clause And FDA's Regulation

In passing the MDA, Congress took steps to preserve the uniformity of the new federal regulatory scheme as well as to protect innovations in device technology from being "stifled by unnecessary restrictions" imposed by state and local governments. H.R. Rep. No. 94-853, at 12, 45 (1976). Specifically, Congress included the following preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any* requirement –
>
> (1) which is different from, or in addition to, *any* requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device *or to any other matter included in a requirement* applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). The only exception to this sweeping command is for state requirements that the FDA elects to exempt from preemption under 21 U.S.C. § 360k(b).

The FDA has issued a regulation interpreting the MDA's preemption clause, 21 C.F.R. § 808.1(d), which provides that "[s]tate or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device." The regulation also states that Section 360k(a) "does not preempt State or local requirements of general applicability." *Id.* § 808.1(d)(1).

C. This Court's Decision In *Medtronic* v. *Lohr*

This Court interpreted the MDA's preemption clause and FDA's regulation in *Lohr*. The case involved a "grandfathered" medical device that had been cleared through the 510(k) process, which involves only a "limited form of review" by FDA. 518 U.S. at 478. This Court took pains to contrast the 510(k) process

with the far more "rigorous" PMA process. 518 U.S. at 477-78; see also *id.* at 479, 494.

Three separate opinions combined to resolve the issues before the Court in *Lohr*. Five Members of the Court concluded, as a threshold matter, that Section 360k(a)'s reference to state "requirements" includes requirements imposed under the common law.[2] The Court unanimously held that claims embodying state requirements that are *identical* to applicable federal requirements are not preempted by the MDA; and a 5-4 majority ruled that the Lohrs' manufacturing and warning claims also were not preempted. The Court also held that, because the 510(k) process does not impose *any* federal design "requirements," it does not preempt state design claims. 518 U.S. at 492-94; *id.* at 513 (O'Connor, J.). Justice Breyer cast the deciding vote with respect to Section 360k(a)'s coverage of common-law requirements and the non-preemption of the Lohrs' manufacturing and warning claims.

The Court's 5-4 holding that the manufacturing and warning claims were not preempted turned on the *general applicability* of the federal regulations imposing manufacturing and labeling requirements – regulations that apply not just to a single medical device or class of devices but to virtually all devices. In this connection, both Justice Stevens's opinion and Justice Breyer's concurrence relied on the FDA's regulation interpreting Section 360k(a) as preempting "[s]tate or local requirements * * * only when the [FDA] has established *specific* counterpart regulations or there are other *specific* requirements applicable to a particular device." 21 C.F.R. § 808.1(d) (emphasis added).[3] The focus of

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[2] See 518 U.S. at 511 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part) ("If § 360k(a)'s language is given its ordinary meaning, it *clearly* pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA * * * .") (emphasis added); *id.* at 504-505 (opinion of Breyer, J.) (same).

[3] See 518 U.S. at 495 (Stevens, J.) ("our interpretation of the pre-emption

Justice Breyer's tie-breaking concurring opinion was on the pertinent *federal* (as opposed to the *state*) requirements. 518 U.S. at 507 (Breyer, J.) ("Insofar as there are any applicable *FDA requirements* here, those requirements, even if numerous, *are not 'specific' in any relevant sense.*") (emphasis added); *ibid.* ("[N]o law forces the FDA to make *its requirements* pre-emptive if it does not think it appropriate.") (emphasis added).

D. The FDA's Current Views On The Scope And Importance Of Preemption With Respect To PMA Devices

As the Solicitor General's brief at the petition stage explains (at 17), the FDA interprets Section 360k(a) as expressly pre-empting state tort claims that seek to impose different or additional requirements on devices that have won premarket approval. More specifically, FDA takes the view that "the agency's approval" of a device "through the PMA process does impose specific requirements for the product, including requirements for its design, manufacturing, performance, labeling, and use." U.S. Br. at *14, *Horn* v. *Thoratec Corp.*, No. 02-4597, 2004 WL 1143720 (filed May 14, 2004) ("U.S. *Horn* Br."). Building on the holding of a majority in *Lohr* "that state tort law judgments do impose a requirement for purposes of preemption under the MDA," the FDA also interprets Section 360k(a) as preempting "the application by a court of a general common law duty to a specific device." *Id.* at *18.

Equally important, the FDA has explained that "strong public policy considerations" support the agency's interpretation

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statute is *substantially informed* by [FDA's] regulations") (emphasis added); *id.* at 496 (there is a "sound basis" for giving "substantial weight to the agency's view of the statute"); *id.* at 505-06 (Breyer, J.) (it "makes sense" to infer that FDA "possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect"). The majority's reliance on the "specificity" concept was somewhat equivocal, however. It elsewhere stated: "[W]e do not believe that th[e] statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted." *Id.* at 500.

of Section 360k(a) as preempting divergent state tort requirements in this setting. *Id.* at *25. Such "[s]tate common law tort actions," the agency has explained, can "threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling," by allowing "lay judges and juries to second-guess" the scientific judgments made by expert regulators at FDA. *Ibid.* State tort litigation can also cause other detrimental effects that "harm the public health," including the proliferation of "scientifically unsubstantiated warnings," "underutilization of beneficial treatments" by physicians and patients, and even "withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective." *Id.* at *26. Thus, FDA recognizes that the MDA's express preemption clause furthers not only Congress's goal of protecting innovation and reducing regulatory burdens but also its goal of protecting and promoting the public health.

SUMMARY OF ARGUMENT

I. A substantial number of the arguments pressed by petitioner and her supporting *amici* in this case were also advanced and refuted by the parties – and explicitly or implicitly rejected by this Court – in *Medtronic* v. *Lohr*. Petitioner's recycled arguments relating to the text, legislative history, and "purpose" of the Medical Device Amendments, and to the pre-1976 history of tort litigation involving medical devices, all target the conclusion of a majority of this Court in *Lohr* that Section 360k(a)'s reference to state "requirement[s]" includes requirements imposed under the common law. That holding is eminently correct, and is supported by a long line of this Court's decisions construing identical or very similar language in other preemption clauses and recognizing the clear regulatory effect of tort law. Indeed, it would be anomalous – and lead to an irrational and unmanageable patchwork of preemption that Congress could not have intended – to read the MDA's preemption clause as excluding requirements that happen to be based in state common law, because many States have codified their

common law of torts in whole or in part. Although petitioner and her *amici* effectively ask this Court to overrule this aspect of *Lohr*, they come nowhere close to providing the requisite "special justification" needed to overcome *stare decisis* concerns. *Arizona* v. *Rumsey*, 467 U.S. 203, 212 (1984). In fact, all of petitioner's recycled arguments lack merit and were properly rejected in *Lohr*.

II. Under the framework of analysis established in *Lohr*, petitioner's claims are expressly preempted. The PMA process imposes specific federal requirements relating to design, manufacturing, and labeling on an approved device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d). Petitioner's state-law claims seek to impose different or additional counterpart requirements on the Evergreen Balloon Catheter. Moreover, there is substantial evidence in both (1) the legislative history of the MDA, and (2) the FDA's practice of administering exemptions from preemption under 21 U.S.C. § 360k(b), to confirm the Second Circuit's determination that the *Lohr* framework and FDA's regulation necessitate preemption in this setting. See pages 19-26, *infra*.

III. If the Court nevertheless concludes that petitioner's claims are not preempted under the *Lohr* framework, then it should take this occasion to reexamine the FDA's "specificity" gloss on Section 360k(a) that was endorsed in *Lohr* (albeit equivocally; see note 3, *supra*). As a careful examination of the FDA's regulatory notices makes clear, the agency never intended to impose a limit on the *type* of federal requirement that triggers preemption under the MDA. Instead, 21 C.F.R. § 808.1(d)'s reference to "specific FDA requirements applicable to a particular device or class of devices" was intended to make clear that some federal requirement *must actually be in place* (not merely be capable of being put in place) before counterpart state requirements are preempted. The four dissenting Justices in *Lohr* were correct in observing that "[t]he statute makes no mention of a requirement of specificity" (518 U.S. at 512 (O'Connor, J.)), and indeed Section 360k(a) broadly provides

that "any requirement applicable under this chapter" to a device triggers preemption of counterpart state requirements.

As for the FDA's suggestion that Section 360k(a) does not preempt state and local requirements "of general applicability" (21 C.F.R. § 808.1(d)(1)), that interpretation is contrary to the text of the preemption clause (as the Solicitor General recognized in *Lohr*) as well as refuted by the FDA's own exemption practice. The Court's decision to rely on this narrowing interpretation in *Lohr* rested on a misunderstanding of the FDA's prior exemption practice. For all of these reasons, and because a similar "specificity" gloss has been rejected as "irrational" by this Court in other preemption settings (*Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992)), the Court should revisit and overrule its endorsement in *Lohr* of a "specificity" gloss on the broad text of Section 360k(a).

ARGUMENT

I. The Court Should Decline To Reexamine Petitioner's Arguments That Were Raised, And Properly Rejected, In *Lohr*

To read petitioner's opening brief and the briefs of her supporting *amici*, one would never guess that a majority of this Court in *Lohr* concluded that state tort duties imposed through the common law constitute "requirements" within the meaning of 21 U.S.C. § 360k(a). See Pet. App. 20a-21a, 30a-31a; note 2, *supra*. As it turns out, a substantial number of the arguments advanced by petitioner and her *amici* were made and refuted by the parties – and rejected either explicitly or implicitly by this Court – in *Lohr*. Because petitioner and her *amici* offer no reason why these arguments have improved with age and should now be revisited – much less the "special justification" required to overcome *stare decisis* concerns (*Arizona* v. *Rumsey*, 467 U.S. 203, 212 (1984)) – all of these recycled arguments should be rejected out of hand.

A. In *Lohr*, five Members of this Court concluded that Congress's express preemption of "any [state] requirement" that

is "different from, or in addition to," a federal requirement applicable to a medical device (21 U.S.C. § 360k(a)) encompasses requirements imposed through the common law of torts. Nevertheless, petitioner contends in a footnote that "[t]he majority holding in *Lohr* does not resolve the question whether damages claims can ever be considered 'requirements' under § 360k(a)." Pet. Br. 16 n.5; accord Br. of Consumers Union ("CU Br."), at 13 (same). Although petitioner does not provide any citation for this assertion, she no doubt is referring to the statement in Section VI of Justice Stevens's opinion declining to resolve this issue. That portion of the opinion, however, garnered only four votes. See 518 U.S. at 508 (Breyer, J.) ("I do not join Part VI, because I am not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare[.]'"). Indeed, Justice Breyer even gave as an example of a claim that *would* be preempted by the MDA "a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire," where "a federal MDA regulation requires a 2-inch wire." *Id.* at 504.

Even if this issue remained open, there is no good reason to resolve it in petitioner's favor – and many reasons to adhere to the Court's ruling in *Lohr*. In a line of cases involving other preemption clauses that nullify state "requirements," this Court has repeatedly held that the term encompasses requirements imposed by state tort or common law. See, *e.g.*, *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (involving Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(b)); *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005) (involving Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136v(b)); see also *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 662 (1993) (reaching same conclusion as to Federal Railroad Safety Act's preemption of certain state "law[s], rule[s], regulation[s], order[s], or standard[s] relating to railroad safety"). These decisions are controlling here.

Beyond that, this Court's decisions in *Cipollone*, *Medtronic*, *Bates*, and *Easterwood* all build on older decisions that rely on

the same principle or acknowledge the clear regulatory effect of common-law judgments. In *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236 (1959), for example, this Court observed that "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Id.* at 247. Similarly, in *Norfolk & W. Ry. Co.* v. *Train Dispatchers*, 499 U.S. 117 (1991), the Court held that the phrase "all other law, including State and municipal law" simply "does not admit of [a] distinction * * * between positive enactments and common-law rules of liability." *Id.* at 128.

B. In light of the powerful regulatory function of tort litigation today, it would be anomalous to read the MDA's preemption clause as excluding requirements that happen to be founded upon state common law. But there at least are four additional reasons why that result is nonsensical and would lead to absurd results.

First, many States have codified their common-law tort regimes. See, *e.g.*, ARIZ. REV. STAT. ANN. §§ 12-681 to -686 (1992); CONN. GEN. STAT. §§ 52-572m to 52-572q (2004); IND. CODE ANN. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996); LA. REV. STAT. ANN. §§ 9:2800.51 to 9:2800.59 (West 1991). See generally Hermann & Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L.J. 1, 9 n.41 (1996) (collecting other statutes). Under petitioner's view, tort requirements in these jurisdictions would be pre-empted but identical common-law requirements in neighboring States would not. Why should such an absurd design be attributed to Congress?[4]

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[4] Notably, these codifications are not just a recent phenomenon. South Carolina, for example, adopted a product liability statute in 1962, and Maine followed suit in 1973. See S.C. CODE ANN. § 15-73-10 (Law. Co-op. 1993) (adopted 1962); ME. REV. STAT. ANN. tit. 14, § 221 (West 1980) (adopted 1973). Thus, at the time Congress enacted the MDA in 1976, this patchwork was already in existence.

Second, some States that have not enacted comprehensive product liability or tort statutes have nonetheless passed more limited tort reform measures. See, *e.g.*, TEX. CIV. PRAC. & REM. CODE § 82.001 *et seq.* (Vernon 1997); Comment, *The Products Liability Act of 1993: How It Changes Texas Law*, 45 BAYLOR L. REV. 633, 635 (Summer 1993). As a result of such measures, tort claims in these States are based on a hybrid of common law and positive law. Given the hybrid nature of tort law in many jurisdictions, it would be unmanageable – and require a time-consuming threshold judicial inquiry into state tort law – for preemption to turn on whether a requirement is rooted in a statute as opposed to the common law.

Third, the common law of many States originated in early *statutes* or *constitutional provisions* adopting the English common law wholesale as the law of the State. For example, "[i]n 1819, the territorial legislature of Florida adopted a statute declaring the common law of England to be of force in Florida. The statute * * * is still in effect * * * ." *Coastal Petroleum Co.* v. *American Cyanamid Co.*, 492 So. 2d 339, 347 (Fla. 1986) (Boyd, J., dissenting) (discussing FLA. STAT. ANN. § 2.01 (1985)); see also Bradley & Goldsmith, *Customary International Law As Federal Common Law: A Critique of the Modern Position*, 110 HARV. L. REV. 815, 870 n.345 (1997) ("[M]ost states have receiving statutes that incorporate as rules of decision at least part of the common law of England."). Since state common-law doctrines evolved from these early English sources, whose legitimacy and force are in turn contingent upon provisions of state *positive* law, it makes little sense to treat common-law requirements as qualitatively different from statutory requirements.

Fourth, reliance on a distinction between common-law and statutory requirements is especially odd in the area of tort law, where "[c]ompendia such as the torts Restatements help to blur the line between statutes and case law." Bernstein, *The New-Tort Centrifuge*, 49 DEPAUL L. REV. 413, 426 (1999). For all of these reasons, it makes no sense to read into Section 360k(a) an

exception for state requirements that happen to be rooted in the common law. That argument was properly rejected in *Lohr*.

C. Petitioner nevertheless maintains (at 15, 19-20) that the state "requirements" referred to in Section 360k(a) should be understood to exclude common law requirements because (1) the "federal 'requirements'" referenced in Section 360k(a) "flow solely from positive law – the MDA and it regulations"; and (2) the exemption provision, 21 U.S.C. § 360k(b), also refers to "requirements" but logically cannot include common law requirements. Both of these arguments were advanced in *Lohr*. See Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 11-12, 18, 24-25; Nos. 95-754, 95-886 Reply Br. Cross-Pet. Lohrs, at 8-9. Both were refuted by Medtronic and by the Solicitor General. See, *e.g.*, Nos. 95-754, 95-886 Br. for Cross-Resp. Medtronic, at 12-13, 16-17. For example, the Solicitor General explained:

> The problem with [the Lohrs'] reasoning is that the limitation on the type of federal provisions that have preemptive effect is not attributable to the term "requirement." It is, instead, attributable to the words that modify "requirement." A state provision may be preempted only by a federal requirement "applicable under this chapter." 21 U.S.C. 360k(a). It is the latter phrase that limits the federal provisions having preemptive force to those imposed by the FDCA and implementing regulations, rather than by common law.

Nos. 95-754, 95-886 U.S. Br. 16-17; see also *id.* at 18-19 (refuting argument that the exemption provision, Section 360k(b), excludes common law requirements).

D. Next, petitioner and her *amici* argue that state common law requirements fall outside of Section 360k(a) because "general common-law duties are not requirements 'with respect to a device.'" Pet. Br. 15 (quoting § 360k(a)); accord AARP Br. 4; AAJ Br. 2-3, 10-11. The same argument was raised in *Lohr*. See Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 12, 19-21; Nos. 95-754, 95-886 Reply Br. Cross-Pet. Lohrs, at 5-7. And it

was refuted by Medtronic and the Solicitor General. See, *e.g.*, Nos. 95-754, 95-886 Br. for Cross-Resp. Medtronic, at 13-15. As the Solicitor General correctly observed, the argument is "strained as a grammatical matter":

> Section [360k(a)] provides in relevant part that no State "may establish or continue in effect *with respect to a device intended for human use* any requirement * * * which is different from [a federal requirement]" * * *. The Lohrs read the italicized phrase as modifying "requirement" * * *. But the "with respect to" phrase cannot modify the word "requirement," because "requirement" comes *after* that phrase. Rather, the phrase modifies the words ("establish or continue in effect") that come immediately *before* it. * * * The phrase * * * preserves the authority of a State to have [a] requirement in effect insofar as it applies to things *other than* medical devices. By allowing in this manner for partial preemption of state "requirement[s]," the "with respect to" clause suggests that such a requirement *may be one of general applicability*.

Nos. 95-754, 95-886 U.S. Br. 17-18 (emphasis altered).

E. In a final textual argument, petitioner and her *amici* also point to 21 U.S.C. § 360h, which they describe as a "savings clause" demonstrating that "Congress expected that state-law claims would proceed against device manufacturers." Pet. Br. 13; see also *id.* at 20-21; CU Br. 17. Here again, this argument was raised and soundly refuted in *Lohr* (so much so that none of the *Lohr* opinions even mentions this provision). Compare Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 12, 27-28 and Nos. 95-754, 95-886 Reply Br. Cross-Pet. Lohrs, at 10 with Nos. 95-754, 95-886 Br. for Cross-Resp. Medtronic, at 17-18 (explaining that Section 360h has to do only with compliance with certain administrative orders issued by FDA and its "reference to * * * liability is not necessarily a reference to personal injury tort claims" as opposed to contractual liability). Even if the provision does refer to tort liability, it would show only that Congress expected that *some* tort claims would not be preempted

by Section 360k(a) – a point independently established by *Lohr* as well as by the MDA's exemption provision.

F. Finally, petitioner and her *amici* advance a hodgepodge of additional arguments based on the legislative history of the MDA, the history of tort litigation involving devices, and the statutory "purpose" of protecting consumers. See Pet. Br. 15-18;AAJ Br. 2; CU Br. 7-10; AARP Br. 2; see also Pet. App. 45a (Pooler, J., concurring in part and dissenting in part) (similarly invoking legislative history). These arguments, they suggest, show that Congress could not possibly have intended to include common law "requirements" in Section 360k(a).

Every one of these arguments was raised in *Lohr*. See Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 28-34; Nos. 95-754, 95-886 Br. for Resp. Lohrs, at 37-41. Every one was implicitly rejected by the five Justices who concluded that Section 360k(a)'s reference to "requirements" includes requirements imposed by state common law. Petitioner has offered no new or persuasive reason – none – why this Court should revisit this holding in *Lohr*.

In any event, these arguments are all unavailing. For starters, petitioner is simply wrong to suggest that "[i]n 1976, for Congress to have preempted damages claims without providing an alternative means of compensation would have been unprecedented." Pet. Br. 18. In fact, Congress did just that in 1969 when it amended the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(b) (see *Cipollone*, *supra*); in 1970 when it passed the Federal Railroad Safety Act, 49 U.S.C. § 20106 (see *Easterwood*, *supra*); and again in 1972 when it amended the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136v(b) (see *Bates*, *supra*). It is thus hardly unprecedented (or even surprising) that Congress would use the same term – "requirement" – to preempt common law requirements in 1976 when it passed the MDA.

Equally unavailing are the arguments based on the MDA's legislative history and "purpose" and on the history of tort

litigation involving devices.[5] The last argument overlooks the seismic changes in the American law of product liability that occurred beginning in the 1960s, not long before Congress amended the MDA. To the extent Congress in 1976 acted against a backdrop of tort litigation, it was tort litigation that looked vastly different from the tort litigation of today. See generally No. 05-1342 Br. of the Chamber of Commerce of the United States, *Watters* v. *Wachovia Bank, N.A.*, at 18-20.

Finally, petitioner's argument based on the statutory "purpose" of protecting consumers and furthering the public health ignores the possibility – which FDA itself has recognized (see pages 6-7, *supra*) – that state tort litigation can *undermine* the public health in a variety of ways (by causing overwarning, spurring manufacturers to provide warnings that FDA has rejected as scientifically unfounded, discouraging beneficial uses of devices, and impeding innovation). The argument also assumes incorrectly that Congress's purpose in passing the MDA was unitary. In fact, Congress enacted a "balanced regulatory proposal" that sought *not only* to protect consumers from unsafe and ineffective devices (principally by conferring new authority on the FDA) *but also* to encourage device innovation and reduce the burdens on interstate commerce. See pages 2, 4, *supra*. As the Second Circuit correctly observed, "a finding of preemption is consistent with" the latter purposes. Pet. App. 34a.[6]

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[5] This Court has routinely refused to take the "extraordinary" step of "requir[ing] legislative history to confirm the plain meaning of" a statute. *Bourjaily* v. *United States*, 483 U.S. 171, 178 (1987). See also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669 n. 2 (1990) (statute can have effects not explicitly mentioned in its legislative history).

[6] Petitioner and various *amici* repeatedly invoke the so-called "presumption against preemption" in urging this Court to reject the preemption defense in this case. See Pet. Br. 13, 21; Brief of Public Health Advocacy Institute ("PHAI Br."), at 2-16. The short answer to this argument is that the presumption is *already* reflected in the framework adopted in *Lohr* for analyzing express preemption. Several of petitioner's *amici* also invoke a report authored in 1991 by then-Judge

II. Under The Framework Of Analysis Established In *Lohr*, Petitioner's Claims Are Expressly Preempted

Once petitioner's recycled arguments are set to one side, this case is easily resolved in respondent's favor under the *Lohr* framework. By its plain terms, Section 360k(a) preempts "any" state "requirement" that is "different from, or in addition to" a counterpart federal requirement that applies to a medical device, so long as the state requirement (1) "relates" either "to the safety or effectiveness of the device or to any other matter included in" a federal requirement, and (2) has not been exempted from preemption by FDA. 21 U.S.C. § 360k(a). In *Lohr*, a majority held that judgments in state tort suits qualify as state "requirements" covered by Section 360k(a). See Pet. App. 20a-21a. Relying on 21 C.F.R. § 808.1(d), a different majority in *Lohr* also suggested that, for federal requirements to trigger preemption under Section 360k(a), they must be "specific" to a device or class of devices. Pet. App.18a-19a.[7]

Kenneth Starr that expresses concern about the doctrine of implied "obstacle" preemption. See PHAI Br. 4, 14-15; AAJ Br. 9 n.3. This case, however, involves express preemption. In any event, Dean Starr's views about the doctrine of preemption have changed in recent years in response to fundamental changes in the legal landscape. See Starr, "Preface," in FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS, at xv (AEI eds. R. Epstein and M. Greve 2007).

[7] The concept of "specificity" is ambiguous. A requirement can be "specific" in *content* (as in Justice Breyer's example in *Lohr* of a 2-inch wire requirement, which is specific when compared to a more generalized duty to use reasonable care in the design of a product). Alternatively, a requirement can be "specific" in *applicability* (as where it applies to a single device or class of devices). FDA's regulation makes clear, however, that it is the *latter* gloss that the agency intends for the state "requirements" covered by Section 360k(a). See 21 C.F.R. § 808.1(d)(1) (Section 360k(a) "does not preempt State or local requirements of general *applicability*") (emphasis added). At the same time, *Lohr* makes clear that common law duties that apply generally even to products other than devices may become "specific" where, as here, they are applied to a particular medical device in the course of litigation.

In *Lohr*, the Court held that certain federal labeling and good manufacturing practices (GMP) requirements, which applied generally to *all* medical devices, were not sufficiently "specific" to trigger preemption. Those regulations are distinguishable from the regulations governing the PMA process because the former apply, "with a few limited exceptions," to "every medical device." 518 U.S. at 497. In contrast, FDA's requirements relating to the PMA process – even viewed in the abstract, apart from their specific application to the Evergreen Balloon Catheter – are limited to a *single regulatory class* of medical devices: devices for which premarket approval is sought. The FDA has acknowledged that "specific FDA requirements applicable to a particular device *or class of devices*" trigger express preemption under the MDA. 43 Fed. Reg. 18661, 18662 (1978) (emphasis added).

In any event, a grant of premarket approval imposes a variety of design, labeling, and manufacturing requirements on the specific device that is approved. By its very nature, PMA approval is a *specific* determination by FDA that a *particular* device is reasonably safe and effective, based on FDA's review of data relating exclusively to that device. See *Buckman*, 531 U.S. at 348 (PMA process "involves a time-consuming inquiry into the risks and efficacy of *each* device") (emphasis added).

As the Second Circuit recognized in this case (Pet. App. 2a, 23a), the vast majority of federal and state courts to have addressed the question – before as well as after *Lohr* – have concluded that the PMA process imposes "specific" federal requirements on approved devices. Most courts have also concluded – correctly – that federal requirements imposed in the PMA process preempt state-law tort claims like those asserted by the petitioner in this case, which seek to impose *different* requirements relating to the design, manufacture, and labeling of a medical device. These conclusions, of course, finds further support in the FDA's interpretation of Section 360k(a), which under *Lohr* is entitled to substantial weight. Pet. App. 37a-38a.

Respondent's brief explains in detail how the premarket approval process works and the legal effect of FDA approval. See also Pet. App. 8a-10a, 25a-27a.[8] It also persuasively demonstrates that, under the *Lohr* framework, petitioner's state-law claims impose "requirements" within the meaning of Section 360k(a) that differ from, or are in addition to, the federal requirements applicable to the Evergreen Balloon Catheter. See also Pet. App. 30a-32a. Rather than repeat respondent's analysis here, we focus below on the substantial evidence from both (1) the legislative history of the MDA, and (2) the FDA's practice of administering exemptions from preemption under 21 U.S.C. § 360k(b), which strongly confirms the Second Circuit's conclusions with respect to preemption.

A. The Legislative History And FDA's Exemption Practice Confirm That The PMA Process Imposes "Requirements" That Are "Specific"

Petitioner concedes in her brief (at 25-26) that, if the FDA determines that a medical device either "could not be marketed without a federal PMA" or, on the contrary, "did not require [a federal] PMA," that decision would impose a federal "requirement" on the device within the meaning of Section 360k(a) that in turn would "preempt a state requirement that the device undergo" premarket approval before a *state* agency pursuant to *state* law. As petitioner is constrained to admit (at 25), on many occasions the FDA has made clear that the federal requirement of premarket approval triggers express preemption under Section

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[8] Petitioner's contention that PMA approval imposes no requirements *at all* on the device not only misunderstands how the regulatory scheme works but also ignores the many provisions of the MDA that refer to "requirements" imposed by FDA through the PMA process (pursuant to 21 U.S.C. § 360e). See, *e.g.*, 21 U.S.C. § 331(e) (prohibiting, among other things, the "failure to establish or maintain" records "required under" Section 360e(f)); *id.* § 351(f)(1)(A)(I), (B)(I), (c) (in sections relating to adulterated devices, referring to "require[ment]" of having premarket approval); *id.* §§ 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 382(a)(2)(A).

360k(a). See 43 Fed. Reg. 18661, 18664 (1978); accord 45 Fed. Reg. 67321, 67322-23 (1980); 44 Fed. Reg. 19438, 19439 (1979). Petitioner also concedes that, in the absence of an exemption granted by FDA, a state provision such as California's Sherman Food, Drug, and Cosmetic Law would be expressly preempted. Pet. Br. 6-7, 25.

The last conclusion rests on clear evidence in the legislative history of the MDA. Specifically, the House Report accompanying the legislation stated:

> In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation * * * is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices * * * . * * *
>
> In the Committee's view, *requirements imposed under the California statute* serve as an example of requirements that the Secretary should authorize to be continued (provided any application submitted by a State meets the requirements [for exemption] * * *).

H.R. Rep. No. 94-853, at 45-46 (1976) (emphasis added). Thus, the legislative history strongly confirms Congress's understanding that "requirements imposed under the California statute" – including the requirement of premarket approval of each new medical device – would be preempted by Section 360k(a) unless FDA grants an exemption.

These concessions go far toward establishing that PMA approval imposes federal requirements that are "specific" and trigger preemption under Section 360k(a). Contrary to petitioner's suggestion, the House Report's reference to "*requirements* imposed under the California statute" is not limited to the requirement of *obtaining* premarket approval; rather, it envisions that *all* "requirements imposed under the California statute" would be preempted in the absence of an exemption. In other words, the Committee plainly believed that requirements

imposed pursuant to a state PMA process – including requirements relating to a device's design, manufacture and labeling – would be subject to preemption unless exempted. What would have triggered such preemption? The answer is self-evident: The counterpart design, manufacturing, and labeling requirements imposed through the *federal* PMA process.

Nor is this all. The conference committee that chose the final language of the MDA opted for the preemption clause in the House bill (H.R. 11124, 94th Cong., 2d Sess. (1976)) instead of the narrower version in the Senate bill (S. 510, 94th Cong., 1st Sess. (1975)). See H.R. Conf. Rep. 94-1090, at 40 (1976). The Senate bill provided:

> Sec. 903. (a) Whenever a performance standard pursuant to section 513 or *scientific review pursuant to section 514 under this Act is in effect*, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes *any requirements* as to the *performance, composition, contents, design, finish, construction, packaging, or labeling* of such product which are designed to deal with the same device unless such requirements are identical to the requirements of *the Federal requirements*.

S. Rep. No. 94-33, at 72-73 (1975) (emphasis added). The reference to "Section 514" was to the process for premarket scientific review in the Senate bill. Thus, the Senate bill plainly envisioned that federal premarket approval would impose requirements that would have preemptive effect. There is no reason to think that Congress, in choosing the *broader* language of the House bill, intended a *narrower* form of preemption that would not be triggered by federal PMA requirements.

The FDA's exemption practice provides further support for the conclusion that requirements imposed through the PMA process trigger express preemption. Illustrative is a post-*Lohr* advisory opinion issued by the FDA on December 18, 1996, in which the agency opined that certain requirements imposed

through the PMA process on an over-the-counter HIV-test kit (known as the "Home Access" test) preempted divergent requirements imposed under state law. See Addendum ("Add.") 1a-5a (reproducing FDA's advisory opinion). Specifically, the FDA explained (Add. 3a):

> The testing protocol proposed by Home Access and approved by FDA provides for the device to be mailed by the client to the laboratory in a preaddressed envelope contained in the kit. Both the New York and California provisions * * * would require referral to the laboratory by a physician or other licensed health professional rather than by the client himself or herself. These requirements, as applied to the Home Access test system are different from the requirements in FDA's approval order. Consequently, these provisions, as applied to the Home Access test system, are preempted under Section [360k(a)] of the act.

The FDA's exemption practice also refutes any suggestion that "specificity" on the federal side is limited to requirements that apply only to a single medical device. During the period the agency regulated cigarettes as a medical device, for example, several of the exemptions considered by FDA involved federal regulations relating to both cigarettes and smokeless tobacco. See 21 C.F.R. § 897.1 *et seq.* (1998); 62 Fed. Reg. 7390 (1997); 62 Fed. Reg. 63271 (1997).[9] And shortly after the MDA was enacted, the FDA considered – and denied – a request by California seeking an exemption from preemption from the federal good manufacturing practices (GMP) regulations, which

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[9] In its *amicus* brief in *Buckman*, the United States gave various examples of federal requirements that qualify as applicable "to a specific device or set of devices" and thus trigger express preemption. 98-1768 U.S. Br., 2000 WL 1364441, at *12. Those examples include federal requirements that apply to all medical devices that contain natural rubber (21 C.F.R. § 801.437) – in all, *43 different categories* comprising *17,600 different models* of medical devices, including catheters, latex gloves, tracheal tubes, condoms, enema kits, and ophthalmic eyeshields. 63 Fed. Reg. 50660, 50673-50676 (1998).

California had adopted as its own, insofar as California wished to interpret them in a way different from FDA. See 45 Fed. Reg. 67321, 67322 (1980) ("if California interprets or applies the GMP regulations in such a way as to make them different from or in addition to the Federal regulations, then the California requirements *will be preempted* to that extent") (emphasis added). That action, of course, presupposes that the federal GMPs, despite their general applicability to virtually *all* medical devices, have preemptive effect under Section 360k(a). To be sure, this Court in *Lohr* reached the opposite conclusion about the preemptive effect of the federal GMP requirements (evidently without being aware of this evidence from the FDA's exemption practice), but that does not change FDA's prior exemption practice.[10] In sum, the MDA's legislative history and FDA's exemption practice remove any doubt about whether the PMA process imposes preemptive federal requirements.[11]

B. The Legislative History And FDA's Exemption Practice Confirm That Petitioner's Claims Would Impose State-Law "Requirements" That Are "Specific" On The Evergreen Balloon Catheter

In *Lohr*, a majority of this Court concluded that Section 360k(a)'s reference to state "requirements" includes requirements imposed by the common law, even though common law

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[10] Consistent with FDA's early exemption practice, the United States *expressly conceded* in its *amicus* brief in *Lohr* that the requirements imposed in the GMP regulations give rise to preemption of state requirements. See Nos. 95-754, 95-886 U.S. Br., 1996 WL 118035, at *24 n.19 ("We do not dispute that the GMPs impose 'requirement[s]' within the meaning of Section [360k(a)].").

[11] Petitioner's contention that the PMA does not impose design and other requirements because design choices may originate in the manufacturer rather than the agency conflates the genesis of an obligation with whether the obligation is binding. Private parties may petition FDA to make rules and regulations. See 21 C.F.R. §§ 10.25(a), 10.30, 10.40(a)(2). Requirements eventually imposed by the agency are in no way optional just because they originated in the proposal of a private party.

duties are not limited to medical devices but apply to a wide array of products and persons. The reason is straightforward: such duties can be and are routinely applied every day to particular medical devices in product liability litigation. The end result of such specific application of tort law to a particular device is the imposition of device-specific requirements within the meaning of the FDA's regulation. As the Solicitor General explained on behalf of the FDA during the Clinton Administration: "Section 360k(a) does preempt a specific duty of care that is made applicable to a device through application in litigation of a State's common law of torts, if that requirement is different from, or in addition to, a specific requirement imposed by FDA." No. 98-1768 U.S. Br., *Buckman* v. *Plaintiffs' Legal Committee*, 12-13 n.1.

This conclusion is confirmed by evidence from the legislative history of the MDA as well as the FDA's exemption practice. As noted above, petitioner acknowledges that Congress had in mind California's Sherman Food, Drug, and Cosmetic Law when it enacted the exemption provision, 21 U.S.C. § 360k(b). Thus, Congress clearly was of the view that, in the absence of an exemption granted by FDA, this California statute would be preempted by Section 360k(a). The California statute's "requirements," in other words, would fall within Section 360k(a). Significantly, however, California's Sherman Law *did not apply only to medical devices*. Instead, as its full name suggests, the Sherman Act also applied to drugs and cosmetics.[12]

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[12] See, *e.g.*, 21 CAL. HEALTH & SAFETY CODE § 26614 (1984) (providing that "any drug or device" is adulterated if it bears or contains for the purpose of coloring only a coloring additive which is unsafe within the meaning of the Sherman Act); *id.* § 26615 (another provision relating to adulteration of drugs and devices); *id.* § 26618 ("Any drug or device is adulterated if any substance has been mixed or packed with it so as to reduce its quality or strength or if any substance has been substituted, wholly or in part, for the drug or device"); *id.* §§ 26631, 26640, 26641 (provisions regulating misbranding of both drugs and devices). The FDA has concluded that all of the foregoing provisions are preempted by Section 360k(a) but only "to the extent that they apply to devices." 21

Thus, the legislative history confirms that a state requirement could be preempted under Section 360k(a) even if it was in theory applicable to products other than medical devices.

FDA's exemption practice further refutes petitioner's submission that a state requirement can never be "device-specific" if it is traceable to a law that applies to products other than medical devices. The FDA has acted on at least a dozen requests for preemption exemptions for state provisions that apply not only to medical devices but also to other products. See 21 C.F.R. § 808.55(b)(1), (2) (denying exemptions for nine separate provisions of California statute "to the extent that they apply to devices"). See also 21 C.F.R. § 808.51 (1999) (exempting Alabama statute "[t]o the extent that" it applies to medical devices); *id.* § 808.52 (same for Alaska statute); *id.* § 808.94 (exempting Utah statute "[t]o the extent" it applies to medical devices). And FDA has made clear that even "general [state] requirements not applicable to specific devices" are covered by Section 360k(a) once they are "applied to a specific device in such a way as to establish requirements." 45 Fed. Reg. 67321, 67322 (1980). That principle is dispositive here.

FDA's exemption practice since *Lohr* has continued to reflect this understanding. Thus, in evaluating exemption requests for state and local requirements relating to cigarettes and smokeless tobacco, the agency considered several state statutes even though they applied to products other than what the agency then regarded as medical devices. See 62 Fed. Reg. 7390, 7392 (1997); 62 Fed. Reg. 63271, 63272 (1997). For example, the agency considered whether to exempt an Alabama statute that applied to "cigarettes, cigarette tobacco or *cigarette paper*, or *any substitute for either of them*." 62 Fed. Reg. at 7391 (quoting ALABAMA CODE § 13A-12-3 (2007) (emphasis added)). And in the FDA's advisory letter relating to the Home Access HIV-test kit, the agency made clear that "[w]hile state licensing and certification requirements generally are not

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C.F.R. § 808.55(b)(1). See also note 13, *infra*.

preempted under Section [360k(a)] (See 21 C.F.R. 808.1(d)(3)), they are preempted when they impose requirements on a particular device that are different from or in addition to specific counterpart requirements imposed" by federal law. Add. 4a.

III. The Court Should Reconsider The "Specificity" Gloss On 21 U.S.C. § 360k(a)

Under the framework established in *Lohr*, petitioner's claims are preempted by Section 360k(a). But if the Court disagrees with that submission, then it should take this opportunity to revisit and reconsider its equivocal conclusion in *Lohr* that express preemption under Section 360k(a) applies only to "specific" requirements. See note 3, *supra*. With all due respect, the four dissenting Justices in *Lohr* were correct when they observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (opinion of O'Connor, J.).

Stare decisis "is a principle of policy rather than an inexorable command." *Hohn* v. *United States*, 524 U.S. 236, 251 (1998) (citation and quotation marks omitted). Although the doctrine has more force in statutory cases, this Court has "never applied *stare decisis* mechanically to prohibit overruling * * * earlier decisions determining the meaning of statutes." *Monell* v. *New York City Dep't of Soc. Servs.*, 436 U.S. 658, 695 (1978). In this case, there is a "special justification" (*Arizona* v. *Rumsey*, 467 U.S. 203, 212 (1984)) for revisiting this aspect of *Lohr*: it rests on a clear misunderstanding of the FDA's regulatory notices and exemption practice.

A. The FDA's interpretation of Section 360k(a) was first set forth in the two notices proposing and then promulgating 21 C.F.R. § 808.1(d), which concerns procedures for obtaining exemptions from preemption under 21 U.S.C. § 360k(b). See 42 Fed. Reg. 30383 (1977) (proposing rule); 43 Fed. Reg. 18661 (1978) (final rule). It was in these notices that the agency first put forward its "specificity" gloss on the preemption provision.

A careful examination of these regulatory notices, however, reveals that the specificity concept was intended to be a limitation only on *state* (not on *federal*) requirements under Section 360k(a). As both the 1977 and 1978 notices make clear, the FDA regarded as an open question whether, under the language of Section 360k(a), a federal requirement *must be in existence* before counterpart state requirements are preempted. Thus, in the 1977 preamble to the proposed rule, the agency stated that

> [c]onsistent with his understanding of the intent of Congress, the Commissioner has *narrowly construed* the preemption provision so that section [360k(a)] * * * preempts State and local requirements only when a *particular Federal requirement becomes applicable to a particular device* by operation of the act. This avoids disruption of vital State and local programs * * * and reduces the possibility of a regulatory hiatus that could result if State or local requirements were considered preempted *prior to the time FDA implemented Federal requirements*. The potential for such a regulatory void is real since it will require several years for FDA to implement fully its device regulatory programs.

42 Fed. Reg. at 30383 (emphasis added); accord *id.* at 30384 (same).

In the 1978 notice, FDA pointed out that "[m]any comments" filed in response to the proposed rule had taken issue with the Commissioner's position that a federal requirement must be in place before state requirements are preempted. 43 Fed. Reg. at 18662. "The comments generally argued that *all* State and local medical device requirements were preempted as of May 28, 1976, the date of enactment of the Medical Device Amendments of 1976." *Ibid.* (emphasis added). It was in rejecting this precise argument that the FDA stated, echoing language in its final regulation, that "the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices." *Ibid.* See 21 C.F.R. § 808.1(d) ("State or local requirements are preempted only when the Food and Drug Administration has established

specific counterpart regulations or there are other specific requirements applicable to a particular device * * *.").

Read in the context of the underlying notices, then, 21 C.F.R. § 808.1(d)'s reference to "specific FDA requirements applicable to a particular device or class of devices" was not intended as a limitation on the *type* of federal requirements that would trigger express preemption. By indicating that there must be "specific FDA requirements" in place before preemption occurs, the agency was saying nothing more than that some federal requirement must actually be in place (not merely be capable of being put in place) before counterpart state requirements are preempted. Other regulatory notices also support this interpretation. See, *e.g.*, 45 Fed. Reg. 67321, 67321-22 (1980); 42 Fed. Reg. 9186, 9186 (1977).

B. In adopting the "specificity" requirement as a gloss on Section 360k(a), the *Lohr* majority reasoned that "the FDA has never granted, nor, to the best of our knowledge, even been asked to consider granting, an exemption for a state law of general applicability." 518 U.S. at 499-500. This is untrue. In fact, as explained above, the FDA has *repeatedly* treated state requirements "of general applicability" (21 C.F.R. § 808.1(d)(1)) – in the sense that they have a "purpose" that "relates * * * to other products in addition to devices" (*ibid.*) – as eligible for exemption from express preemption. Perhaps the best example is California's Sherman Food, Drug and Cosmetic Law, which contains numerous provisions that pertain to drugs as well as to medical devices. See note 21, *supra*; 44 Fed. Reg. 19440 (1979); 21 C.F.R. § 808.55(b)(1).[13] Moreover, the FDA also considered

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[13] For example, the FDA has determined that Section 360k(a) preempts a California provision that makes it unlawful "for any person to *advertise* any *drug or device represented to have any effect* in any of the following conditions, disorders, or diseases: * * * (m) [d]iseases or disorders of the ear or auditory apparatus, including hearing loss and deafness." 21 CAL. HEALTH & SAFETY CODE § 26463(m) (1984) (emphasis added). According to the FDA, this provision is preempted "to the extent that it applies to hearing aids." 21 C.F.R. § 808.55(b)(2); 45 Fed. Reg. at 67322.

California's request for an exemption of its GMP requirements, which applied to all kinds of devices. See pages 22-23, *supra*.

Nor is this all. As explained above (at 14), the Solicitor General acknowledged in *Lohr* that the text of Section 360k(a) – and in particular Congress's use of the phrase "with respect to" – in fact "suggests that" a state requirement covered by the preemption clause "may be one of general applicability." Nos. 95-754, 95-886 U.S. Br. 18. The FDA's "specificity" gloss, in other words, is inconsistent with the text of Section 360k(a). And yet FDA's reasons for engrafting the "specificity" limitation on Section 360k(a) in the first place were (1) the supposed absence in the MDA's legislative history of any reference to generally applicable state requirements as imposing undue burdens on interstate commerce (which overlooks or ignores Congress's mention of California's Sherman Law); and (2) a stilted interpretation of the "with respect to" phrase that the Solicitor General in his *Lohr* brief described as "strained as a grammatical matter" and repudiated. See 42 Fed. Reg. at 30384; 43 Fed. Reg. at 18663. Both of the original rationales for the "specificity" gloss on state "requirements" are thus mistaken (and one has been repudiated).

C. A final reason why the Court should abandon the "specificity" gloss is that it makes no sense. Why would Congress have meant to preempt "different" or "additional" state requirements imposed by laws that apply exclusively to medical devices, but to preserve the *very same requirements* if imposed by laws (like California's Sherman Law) that apply to other products as well? In either case, the impact on uniformity and on the federal scheme is exactly the same. Nor is there any good reason to think Congress would have wanted to allow States and local governments to evade preemption through the simple expedient of skillful drafting.

Not surprisingly, this Court has repeatedly rejected invitations to read similar limitations into other express preemption provisions. Illustrative is *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), which involved a provision of the Airline

Deregulation Act of 1978 ("ADA") that "pre-empts the States from 'enact[ing] or enforc[ing] any law, rule, regulation, standard or other provision * * * relating to rates, routes, or services of any air carrier.'" *Id.* at 383 (quoting 49 U.S.C. App. § 1305(a)(1)). The Court categorically rejected the argument that "only state laws specifically addressed to the airline industry are pre-empted, whereas the ADA imposes no constraints on laws of general applicability." *Id.* at 386. Such an interpretation, this Court noted, would create "an utterly irrational loophole." *Ibid.* (emphasis added).[14] That criticism applies with equal force here. Accordingly, the Court should take this opportunity to eliminate this "utterly irrational loophole" from the law of express preemption under the MDA.[15]

CONCLUSION

The judgment of the court of appeals should be affirmed.

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[14]Accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987) (ERISA preemption is not limited to state measures targeting ERISA plans but also includes more general common law tort and contract causes of action); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959) ("Nor has it mattered [in cases involving NLRA preemption] whether the States have acted through laws of broad general application rather than laws specifically directed towards the governance of industrial relations.").

[15] Notably, the United States in *Lohr* did *not* urge this Court to adopt, or even to defer to, the "specificity" concept expressed in 21 C.F.R. § 808.1(d).

Respectfully submitted.

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ADDENDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Rockville MD 20857

DEC 18, 1996

[docket file-stamp omitted]

Robert P. Brady, Esq.
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Dear Mr. Brady:

This is in response to your request for an advisory opinion concerning the preemptive effect of Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) ("the act") on certain New York and California statutes as applied to the HIV-1 Home Test Kits of Home Access Health Corp.

Section 521(a) of the act provides that no State or local government may establish or continue in effect any requirement with respect to a medical device that is different from or in addition to any requirement under the act applicable to the device, which relates to the safety or ineffectiveness of the device or any other requirement applicable to the device under the act. State or local requirements are preempted only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act (21 C.F.R. 808.1(d)).

The Home Access Approval:

On July 22, 1996, FDA approved the Home Access™ HIV-1 Test System ("the Home Access test"). The approval order states that the device is indicated for self-use by people who wish to obtain anonymous testing. The approved collection kit

contains the materials necessary to collect blood specimens in the privacy of the home and to ship the specimens to a qualified dedicated testing laboratory. The client follows instructions in the collection kit to collet a blood specimen and places it in a pre-addressed, prepaid return envelope. The specimens are shipped to a dedicated laboratory meeting Clinical Laboratory Improvement Act (CLIA) requirements and the approval order, Mid-American Technologies, Inc., Olathe, Kansas is the only laboratory qualified to conduct the testing of specimens of the Home Access™ HIV-1 Test System. Testing by any other laboratory would require approval of a premarket approval (PMA) supplement by FDA.

Over-the-Counter (OTC) versus Prescription Use:

You have asked for an advisory opinion concerning the preemptive effect of Section 521 of the act on California and New York requirements which, if applied to the Home Access test, would require that laboratories accept specimens only upon the order of a physician or other licensed health professional.

Section 1288 of the California Business and Professions Code provides that: [a]ny person conducting or operating a clinical laboratory may accept assignments for tests only from and make reports only to persons licensed under the provisions of law relating to the healing arts or their representatives.

The California Business and Professions Code Section 1246.5 provides an exception to this requirement for certain listed tests (not including the Home Access test) and further provides that a test may be added to the list, after it has been approved by FDA for OTC use. It does not appear that California has at this time added the Home Access test to this list.

The New York Comp. Codes R. & Regs tit. 10, 58-1.7(b) provides that: clinical laborator[ies] shall examine specimens only at the request of licenced physicians or other persons authorized by law to use the findings of laboratory examinations

in their practice or the performance of their official duties. New York does not provide for any exceptions to this requirement.

As noted above, in approving the Home Access test, FDA made a determination that the test may be distributed for self-use by persons who wish to obtain anonymous HIV testing, in other words for "over-the-counter" (OTC) use. The testing protocol proposed by Home Access and approved by FDA provides for the device to be mailed by the client to the laboratory in a preaddressed envelope contained in the kit. Both the New York and the California provisions cited above would require referral to the laboratory by a physician or other licensed health professional rather than by the client himself or herself. These requirements, as applied to the Home Access test system are different from the requirements in FDA's approval order. Consequently, these provisions, as applied to the Home Access test system, are preempted under Section 521 of the act.

State Laboratory Permit Requirements:

You also ask for an advisory opinion on whether the following provisions concerning laboratories performing HIV testing are preempted as applied to the Home Access test:

1. N.Y. Comp. Codes R. & Regs. tit. 10, at 58-1.1(a) This provision requires that clinical laboratories obtain a permit from the New York Commissioner of Health and that a permit may not be issued to a laboratory unless it has been inspected by the Department of Health. It further provides that a clinical laboratory shall perform only those tests that are within the categories stated on its permit.

2. Section 1039.2 of the California Code of Regulations. This section requires that laboratory personnel be certified for the type and complexity of testing performed.

3. Section 1230(e) of the California Code of Regulations. This section provides that approved laboratories shall perform confirmatory testing on all specimens with a positive HIV

screening result using FDA approved Western blot kids or the immunofluorescence method developed and used by the California Department of Health Services.

Both of the statutes contain provisions making these requirements applicable to out of state laboratories accepting specimens from these states.

While state licensing and certification requirements generally are not preempted under Section 521(a) (See 21 C.F.R. 808.1(d)(3)), they are preempted when they impose requirements on a particular device that are different from or in addition to specific counterpart requirements imposed on that particular device under the act. The approval order for the Home Access test specifically requires that testing be conducted by the Mid-American Technologies, Inc. (MAT) laboratory. Before approving the MAT laboratory, FDA performed an inspection of the laboratory to determine whether it was in compliance with all applicable regulations governing matters such as process and software validation, buildings, environment, and personnel. The inspectors witnessed a validation run of assays of the Home Access test kit. The New York provisions in 58-1.1(a) above and Section 1039.2 of the California Code of Regulations, if applied to MAT testing under the Home Access test system would impose licensing and certification requirements with respect to the Home Access test that are in addition to, and perhaps different from, specific requirements under the approval process and, consequently, are preempted under Section 521 of the act. These provisions are preempted only to the extent that they are applied to MAT with respect to the Home Access test kit.

Similarly, the requirements for confirmatory testing set out in Section 1230(e) of the California Business and Professions Code are also preempted, as applied to the Home Access test kit. The FDA approval requires confirmatory testing only with a test approved by FDA. The California requirement for confirmatory testing allow for confirmatory testing with an immunofluorescence method not approved by FDA and, therefore, is different from the FDA requirements.

If you have any questions about this advisory opinion, you may contact Joseph M. Sheehan of our Center for Devices and Radiological Health at (301) 827-2974.

Sincerely yours,

/s/

William B. Schultz
Deputy Commissioner for Policy